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The following article by Dr. Lester Grinspoon provides a good overview of the medical and legal issues surrounding medical cannabis today.			
<b>Medical Marihuana in a Time of Prohibition</b> <b>International Journal of Drug Policy, April, 1999</b> <b>Lester Grinspoon, M.D.</b>			
"A new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die and a new generation grows up that is familiar with it."—Max Planck			
The medical value of marihuana has become increasingly clear to many physicians and patients. There are three main reasons for this. First, it is remarkably non-toxic. Unlike most of the medicines in the present pharmacopeia, it has never caused overdose death. Its short-term and long-term side effects are minimal compared to medicines for which it will be substituted. Second, once patients no longer have to pay the prohibition tariff, it will be much less expensive than the medicine it replaces. Third, it is remarkably versatile. Case histories and clinical experience suggest that it is useful in the treatment of a wide range of dozen symptoms and syndromes, and others will undoubtedly be discovered in the future.			
As clinical evidence of marihuana's medical efficacy and safety accumulates and first-hand experience of its value becomes more common, the discussion is turning to how it should be made available. When I first considered this issue in the early 1970s, I was struck by the fact that the medical community was largely unaware of the existence of marihuana, let alone its potential value.			

1970s, I thought the main problem was its classification in Schedule I of the Comprehensive Drug Abuse and Control Act of 1970, which describes it as having a high potential for abuse, no accepted medical use in the United States, and no accepted safety for use under medical supervision. At that time I naively believed that a change to Schedule II would be a major obstacle, because clinical research would be possible and prescriptions would eventually be allowed.

I was the first witness at a joint meeting of the Drug Enforcement Administration and the Food and Drug Administration convened to consider a petition for rescheduling introduced by the National Organization for the Reform of Marijuana Laws in 1972. At that time I had already come to believe that the greatest harm in recreational use of marijuana came not from the drug itself but from the effects of prohibition. But I saw that as a separate issue; I thought that, like opiates and cocaine, marijuana could be used medically while remaining outlawed for other purposes. I also thought that once it was transferred to Schedule II, research on marijuana would be pursued eagerly, since it had shown such interesting therapeutic properties. From that research we would eventually be able to determine how it should be used medicinally, how prescriptions could be written, and who would be responsible for quality control. Twenty-five years later, I have begun to doubt this. It would be highly unlikely that marijuana could be approved as a legitimate medicine within the present federal regulatory system, but it now seems more likely.

First, I should note that cannabis has already been a legally accepted medicine in the United States several times. When it was dropped after the passage of the Marihuana Tax Act, it was one of the drugs listed in the U.S. Pharmacopoeia. If it had not been removed at that time, it would have been grandfathered into the Comprehensive Drug Abuse and Control Act of 1970 as a prescription drug, just as cocaine and morphine were. Again, in the late 1970s and early 1980s, cannabis was used by hundreds of patients (mainly in the form of synthetic tetrahydrocannabinol) in projects conducted by several of the National Institutes of Health for the treatment of nausea and vomiting in cancer chemotherapy. This episode ended because each state program I visited was burdened with an enormous federal paperwork burden that was more than the physicians and administrators involved could handle. In 1976 the federal government itself approved the use of cannabis as a medicine by instituting the Compassionate Use Program, under which physicians could obtain an individual Investigational New Drug application (IND) for a patient to receive cannabis. This program too was so bureaucratically burdened that in the course of its history only about three dozen patients received marijuana, and only eight are still receiving it. When the program was discontinued permanently in 1992, Dr. Thomas Mason, the chief of the Public Health Service, gave the following reason: "If it is perceived that the Public Health Service is going around giving marijuana to folks, there would be a perception that this stuff can't be so bad. It gives a bad example to the mind doing that if there is no other way of helping these people...But there is not a shred of evidence that smoking marijuana assists a person with AIDS." In effect, this action was analogous to the recall of a prescription drug, without any evidence of toxic effects to support it.

Today, even transferring marijuana to Schedule II would not be enough to make it available as a prescription drug. It must undergo rigorous, expensive, and time-consuming tests before it is approved by the Food and Drug Administration for marketing as a medicine. The purpose is to protect the consumer by establishing safety and efficacy. Because no drug is completely safe or always efficacious, an approved drug has presumably satisfied a risk-benefit analysis. When physicians prescribe for individual patients they conduct an informal analysis of a similar kind, taking into account not just the safety and efficacy, but its risk and benefits for a given patient with a given condition. The formal drug approval process is designed to provide physicians with the information they need to make this analysis.

This system is designed to regulate the commercial distribution of drug company products and protect the public against false or misleading claims about their efficacy and safety. The drug is generally a single synthetic chemical the company develops and patents. It submits an application to the Food and Drug Administration and tests it first for safety and then for clinical efficacy and safety. The company must present evidence from double-blind controlled studies showing the drug is more effective than a placebo and as effective as available drugs. Case reports, expert opinion, and clinical experience are not considered sufficient. The standards have been tightened since the present system was established in 1962. Applications that were approved in the early 1960s would be approved today on the basis of the same evidence.

Certainly we need more laboratory and clinical research to improve our understanding of medicinal cannabis. We need to know how many patients and which patients with each symptom or syndrome are likely to find cannabis more effective than other drugs. We also need to know more about its effects on the immune system in immunologically impaired patients, in combination with other medicines, and its possible uses for children.

But I have come to doubt whether the FDA rules should apply to cannabis. There is no question about its safety. It is one of humanity's oldest medicines, used for thousands of years by millions of people with very little evidence of significant adverse effects. More is known about its adverse effects than about those of most prescription drugs. The American government conducted a decades-long multimillion-dollar research program in a futile attempt to demonstrate toxic effects that would justify the prohibition of cannabis as a nonmedical drug. Should time and resources be wasted to demonstrate for the FDA what is already so obvious?

As for efficacy, some believe that has been proven too, although most disagree. During the 1970s and '80s several government-sponsored research projects I mentioned suggested that marijuana had advantages over both oral tetrahydrocannabinol and other medicines in the treatment of nausea and vomiting from cancer chemotherapy. But as long as the drug can be given only to rigorous double-blind controlled studies, the case for marijuana has not been made. The case for a useful medicine rests almost entirely on case reports and clinical experience, just as it did in the late 19th and early 20th centuries.

A double-blind controlled study may be the best way to prove the relative value of a new medicine whose advantages over established drugs are not obvious. But it is not the only way to demonstrate efficacy. The focus of controlled trials is on statistical differences in effects in groups of patients, but medicine has always been concerned mainly with individual patients. Individual needs can be obscured in such experiments, especially when little effort is made to identify distinctive characteristics in their responses. The value of case reports and clinical experience is often underestimated. They are the source of knowledge of synthetic medicines as well as plant derivatives. Controlled experiments were not needed to recognize the therapeutic potential of chloral hydrate, barbiturates, aspirin, curare, or lithium. The therapeutic value of penicillin was recognized after it had been given to only six patients. Similar evidence revealed the use of propranolol for hypertension, diazepam for status epilepticus, and imipramine for childhood enuresis. These drugs had originally been approved for other purposes.

As early as 1976 several small and imperfect studies, not widely known in the medical community, had shown that aspirin could prevent a second heart attack. In 1988 a large-scale experiment demonstrated effects so dramatic that the researchers decided to stop the experiment to publish the life-saving results. On one estimate, as many as twenty deaths a year might have been prevented from the mid-1970s to the late-1980s if the medical establishment had been able to recognize the value of aspirin. The lesson is suggestive: marijuana, like aspirin, is a substance known to be useful and with enormous potential medical benefits. There is one contrast, however; it was impossible to be sure about aspirin on heart attacks without a long-term study involving large numbers of patients, but innumerable reports show that cannabis often brings immediate relief of suffering that can be measured in a single person.

Case histories are, in a sense, simply the smallest research studies, and the case reports on marijuana are numerous and often persuasive. There is an experimental method known as the N-of-1 clinical trial, or the single-patient randomized trial. In this type of experiment, active and placebo treatments are administered randomly in alternation or succession to a patient. This method is often useful when large-scale controlled studies are impossible or inappropriate because the disorder is rare, the response is atypical, or the response to the treatment is idiosyncratic.

Some medical marijuana patients I know of carried out similar experiments on themselves by alternating periods of use with periods of no use. They had such symptoms as nausea and vomiting, muscle spasms, compromised vision, and debilitating pruritus. It is certain that cannabis won its reputation as a medicine partly because many other patients in the world have carried out the same kind of experiment. Admittedly, in these experiments cannabis could not be a completely random drug and there was no placebo, but in any case its psychoactive effects are usually unmistakable. Patients or observers could be deceived by a placebo. Case histories and other reports of clinical experience are often disparagingly dismissed as merely "anecdotal" evidence, which is said to be irrelevant because only apparent successes are counted and failures are ignored. It is true that cannabis may be useful for some people with, say, multiple sclerosis, chronic pain, or depression, and not for others. But cannabis is so safe that if even a few patients with a given symptom can find some kind of relief, they should be allowed access to it.

Even if it made sense to put marijuana through the FDA process, there would be other problems in taking the cor

route to medical legitimacy. As I have mentioned, FDA procedures are designed for single chemical compounds, but cannabis is a plant material containing many chemicals. Also, it is taken chiefly by smoking, and no other drug in the present pharmacopeia is delivered by this route. Furthermore, thousands of people are already getting relief from cannabis. They would not be risking severe penalties if they did not believe that it was more useful than conventional medicines. Can we ask them to put their pain and suffering on hold for years while the established procedures grind away?

Patients, their families, and others are becoming increasingly impatient for a legal means of obtaining medical cannabis. The most dramatic manifestation of this impatience has been the referenda allowing distribution of medicinal cannabis that have been passed in several states. In 1996 California became the first state to approve such a law. Within weeks of the law's passage, more than a dozen cannabis clubs opened to help sick people in need of relief, and the membership of one quickly grew to over 100. Many Americans believe that this is the best temporary approach to the problem of making medical cannabis available.

Among those who understand the present importance of the cannabis clubs or cooperatives, there are two views of their organization. One model follows the conventional delivery system for medicine: the patient who needs medicinal cannabis (read medicine) goes to the buyers club (read pharmacy) and presents a note from a physician which certifies that the patient has a condition for which the physician recommends cannabis (read prescription) to the staff of the buyers club (read pharmacist). In both the doctor and the buyers club behave responsibly and ethically, only those who have a certified need for the medicine receive it, and those who are certified now have a reliable source. They are relieved of the anxiety of having to find a source on the street or grow their own.

In a buyers club of this kind, the patient is of course not expected to take the medicine on the premises. In contrast to the conventional distribution model resembles a social club more than a pharmacy. The dispensing area is plastered with menus of products, grades, and prices. Large rooms are filled with brightly colored posters, lounge chairs and sofas, tables, magazine racks, and newspapers. While some people remain only long enough to buy their medicine, most stay to smoke and talk. The atmosphere is animated by conversations, laughter, music, and the pervasive pungent odor of cannabis. The atmosphere is informal and warm, providing support for patients who may be socially isolated and have little opportunity to share concerns about their illnesses. This type of club is a blend of Amsterdam-style coffeehouse, American bar, and medical supply store.

Most people who recognize the importance of the buyers clubs believe that the first model, epitomized by the now closed Oakland Club, is preferable to the second model, represented by the now closed San Francisco Cultivators' Club. The San Francisco model, largely because of the on-site cannabis smoking and relaxed atmosphere, seems more casual and less committed to confirming medical need, and this has made even the supporters of buyers clubs a little nervous. The importance of the social aspect cannot be underestimated. It is becoming increasingly clear that emotional support and help from friends, family, co-workers, and others—plays an important role in battling illness. This support can improve quality of life and may even prolong the life of people with various illnesses, including cancer. The San Francisco Club was not designed by psychiatrists and social scientists to provide supportive group therapy, but there is reason to believe that it did. One of the properties of marijuana may have contributed to its effectiveness: when people use cannabis, they become more sociable and find it easier to share difficult thoughts and feelings. If there is even a kernel of truth to the idea that talking about the stress, setbacks, and triumphs in the battle against an illness can help a patient cope and recover, it is clear that the San Francisco model provides the best kind of environment for the dispensing of marijuana.

Unfortunately, even many supporters of medical cannabis regarded the language of California Proposition 215 as too broad for legal use, cultivation, and distribution of marijuana. The initiatives passed more recently in several states have imposed more tightly drawn limitations. They will not permit cannabis clubs with the medical and psychiatric advantages of the San Francisco model, and they allow such a short list of medical uses that only a few of the patients who could find marijuana helpful will be allowed to use it. But in any case, buyers clubs have to be regarded as a stopgap measure. The federal government is not going to allow the development of a separate distribution system for one medicine. It has already done so in closing most of the California buyers clubs, and if it is as successful elsewhere, they will not long endure.

Other present approaches to making marijuana medically available have even more serious drawbacks. Marijuana is classified as a Schedule I drug, which means that it is legally defined as too dangerous for use even under medical supervision. But for the sake of argument, let us suppose that the government comes to its senses and marijuana is moved to Schedule II. This would allow investigators to do the studies which lead to FDA approval for medical use. But where will the medicine be distributed?

finance these studies come from? New medicines are usually introduced by drug companies, which spend an estimated hundred million dollars or more on the development of each product. They are willing to undertake these costs only if they hope for large profits during the 20 years they own the patent. Obviously pharmaceutical companies cannot support medical marijuana and, in fact, may oppose its acceptance as a medicine because it will compete with their own products. The U.S. government has sufficient resources to explore medical marijuana. But its record on the matter is, to put it mildly, not reassuring. The government has opposed any loosening of restrictions on clinical research with cannabis, including the research needed for FDA approval. I believe the government will ultimately have to provide some support for this research because of public pressure, but it will arrive slowly. A study of marijuana in the treatment of the AIDS wasting syndrome has recently been approved and funded after four years of obstruction. But this happened only because the political climate changed after the California initiative, and even so, the main subject of the study had to be changed from medical marijuana to safety.

But let us suppose that studies are somehow completed showing that marijuana is safe and effective as a treatment for the weight reduction syndrome of AIDS, and physicians are able to prescribe it for that condition. This will present unique problems. When a drug is approved for one medical purpose, physicians are generally free to write off-label prescriptions—they can prescribe it for other conditions as well. Dronabinol (Marinol), a synthetic form of tetrahydrocannabinol, was approved as a prescription drug in 1986 for the treatment of nausea and vomiting in cancer chemotherapy, and later for the treatment of the weight reduction syndrome of AIDS. However, presumably because it was thought to be susceptible to medically important drug interactions, it became the first FDA-approved drug for which off-label use was forbidden. The ban has proved too difficult to enforce, and doctors have prescribed it off-label, although somewhat timidly. If marijuana is approved as a medicine, how should concern about off-label prescriptions be dealt with?

Present state and federal schemes for making cannabis medically available invariably specify that it must be used only in the treatment of illnesses defined as "serious", "life-threatening", "terminal", or "debilitating." Which of the many symptoms and syndromes for which cannabis is useful should be considered "serious?" For example, what about premenstrual syndrome? Surely women who suffer from this disorder consider it a serious problem, and many of them find that marijuana is a useful treatment. What about intractable hiccups or the loss of erectile capacity in paraplegics? The people who suffer from these rare problems know how debilitating they can be.

Generally speaking, the more dangerous a drug is, the more serious or debilitating must be the symptom or illness for which it is approved. Conversely, the more serious the health problem, the more risk is tolerated. If the benefit is very large and the risk is very small, the medicine is distributed over the counter (OTC). OTC drugs are considered so useful and safe that they are allowed to be used without a doctor's permission or advice. Thus, today anyone can buy and use aspirin for any purpose at all. This is permissible because aspirin is considered so safe; it takes "only" one to two thousand lives annually in the United States. The remarkably versatile ibuprofen and other NSAIDs can also be purchased over the counter, because they are considered very safe; "only" 7,000 Americans lose their lives to these drugs annually. Acetaminophen, another common drug, is responsible for about 10% of cases of end-stage renal disease. The public is also allowed to purchase many remedies whose dangers have not been determined and which probably have only placebo effects.

Compare these drugs with marijuana. Today no one can doubt that it is, as DEA Administrative Judge Francis L. Young said, "among the safest therapeutic substances known to man." If it were now in the official pharmacopeia, it would be a strong contender for the title of least toxic substance in that compendium. In its long history, marijuana has never caused a reported overdose death. Yet government schemes for its medical use are always cloaked in language suggesting that it is dangerous to be used except under the most stringent limitations. In several states, medical marijuana initiatives require patients to register, and in two states they will need identification cards to protect them from arrest.

As a Schedule II drug, marijuana would be classified as having a high potential for abuse and limited medical use. As regulations on these drugs are becoming tighter, nine states now require doctors to make out prescriptions for many of them, and in some that one copy can be sent to a centralized computer system that tracks every transaction. In 1989 New York State added benzodiazepines (Valium and related drugs) to the list of substances monitored in this way. Research has shown that many patients in New York who have a legitimate need for benzodiazepines are being denied them, and less effective drugs are being substituted. Increased regulation caused by fear of drug abuse has been to the disadvantage rather than the advantage of patients.

In such situations physicians are often afraid to recommend what they know or suspect to be the best medicine because they might lose their reputations, licenses, and careers. Pharmacies might be reluctant to carry marijuana as a Schedule II drug and physicians would hesitate to prescribe it. Through computer-based monitoring, the DEA could know who was prescribed marijuana and how much. It could hound physicians who by its standards prescribed cannabis too frequently for medical purposes the government considered unacceptable. The potential for harassment would be extremely discouraging. Unlike other Schedule II drugs such as cocaine and morphine, cannabis has many potential medical uses. Many physicians try to persuade their doctors that they had a legitimate claim to a prescription. Physicians would not want the responsibility of making such decisions if they were constantly under threat of discipline by the state. A physician who prescribed cannabis for chronic pain, for example, might be subjected to the same harassment as those whom the DEA considers to be dispensing opioids too liberally. Since the passage of the medical marijuana initiative in California, I have heard from many physicians who say their doctors are afraid to recommend (not prescribe) marijuana because of threats from the federal government, although those threats have been declared by the courts to be legally baseless.

There is actually no case for the present restrictions—unless third-party reefer-madness anxiety counts as a risk. The Schedule II classification of cannabis would not be accurate. It does not have a high potential for abuse, and above all, it does have limited medical uses. For example, a physician might sensibly and safely prescribe it for muscle spasms and chronic pain resulting from a variety of conditions, from paraplegia to premenstrual syndrome. If the government and medical licensing boards insist on tight restrictions, challenging physicians as though cannabis were a dangerous drug every time it was prescribed for any new patient or any new purpose, there will be constant conflict with one of two outcomes: patients do not get the relief they should from this medicine, or they get the benefits by abandoning the legal system for the black market or the back outdoor or closet gardens.

Then there is the question of who will provide the cannabis. The federal government now provides cannabis from Mississippi to eight patients who have residual Compassionate INDs. But surely the government could not or would not grow marijuana for many thousands of patients receiving prescriptions, any more than it does for other prescription drugs. If production is contracted out, will the farmers have to enclose their fields with security fences? How would the marijuana be distributed? If through pharmacies, how would they provide secure facilities capable of keeping fresh supplies? What if more tests are demanded for workers, how would patients who use marijuana legally as a medicine be distinguished from those who use it for other (disapproved) purposes?

If the full potential of cannabis as a medicine were to be achieved in the setting of the present prohibition system, many problems and more would have to be addressed. A delivery system that successfully navigated this minefield would be cumbersome, inefficient, and bureaucratically top-heavy that patients would continue to grow their own or buy it on the black market. The authorities could claim that a legal medical distribution apparatus existed, but most patients would find themselves in the same situation they are in today. The Compassionate IND program, the federal government's last scheme to regulate medical cannabis needs, lasted from 1976 to 1992 but never supplied more than a few dozen patients with cannabis.

Some believe a solution to the "medical marijuana problem" (restricting the use of cannabis for medical purposes) lies in the isolation of individual cannabinoids, the manufacture of synthetic cannabinoids, and the development of new drugs (chemical cousins of cannabinoids). Supposedly, these drugs, sometimes in combination, will make the natural product superfluous. Their use in the form of parenterals, nasal sprays, vaporizers, skin patches, pills, and suppositories will make it unnecessary to expose the lungs to the particulate matter in marijuana smoke. Furthermore, the commercial products may lack psychoactive effects, which is apparently very important to some people. A pain researcher at the Memorial Sloan-Kettering Cancer Institute recently said that he was excited by the new analogs because "the euphoria sparked by cannabinoids...is undesirable in chronically ill patients."

Not everyone will agree that freedom from the psychoactive effects is an advantage, but some cannabinoids and analogs may be preferable to whole smoked or ingested marijuana for other reasons. For example, cannabidiol may be more effective as an anti-anxiety drug when it is taken without THC, which sometimes generates anxiety. Other cannabinoid analogs may occasionally prove more useful than marijuana because they can be administered intravenously. For example, lorazepam, which is used to induce unconsciousness in 15% to 20% of patients who suffer a thrombotic or embolic stroke, an even higher proportion of patients with hemorrhagic stroke, and some who develop a brain syndrome after a severe blow to the head. The cannabinoid analog dexanabinol (HU 211) has recently been shown to limit brain swelling and protect brain cells from damage in these

circumstances. It is apparently not psychoactive and can be given intravenously to an unconscious person.

The modern pharmaceutical laboratory will undoubtedly develop other cannabinoid-related products with properties that marihuana and marihuana extracts lack. There are already two known receptors for cannabinoids with different anatomical distributions and only partially overlapping functions. New agonists, antagonists, and inverse agonists will be developed for these receptors (and possibly for others still to be discovered), some of which may have therapeutic potential. For example, tetrahydrocannabinol and possibly other cannabinoids enhance appetite. Perhaps pharmacologists will develop cannabinoid inverse agonists which inhibit appetite and act as nontoxic weight reduction medicines. A better understanding of cannabinoid functions will also result from this kind of research.

But these encouraging developments have a worrisome downside. South American Indians have chewed the coca leaf for thousands of years with little apparent abuse and few ill effects, but since the isolation of methylbenzoyllecgonine (the leaf's other natural alkaloids), some users have developed serious problems. Similarly, opium in its natural form is less than, say, the potent synthetic opioid fentanyl. HU 211 (dexamabinol) is not psychoactive, but its stereoisomer, HU 308, synthesized in the same laboratory, is hundreds of times more psychoactive than THC. Other analogs may be equally dangerous. The danger is that they will bear the same relationship to marihuana that fentanyl bears to opium.

There are other reasons why isolated cannabinoids and cannabinoid analogs will probably never completely displace marihuana itself as a medicine. It was once widely believed that the availability of dronabinol would make medical marijuana superfluous. Dronabinol is packed in sesame oil, partly for easier absorption, but also because it makes smoking marijuana less palatable and therefore was thought to make nonmedical use unlikely. But patients have generally not found dronabinol to be as useful as whole smoked marihuana. Even among those who judge it equally effective, many find that street marihuana is less expensive. If the advent of prescribable dronabinol did not make marihuana medically obsolete, it is hard to believe that the arrival of new analogs will do so. I believe that many if not most patients who could get benefits from the new analogs will choose instead to smoke the more easily accessible and less expensive marihuana.

In evaluating the prospects for cannabis analogs, we must consider what a pharmaceutical product requires for commercial success.

(1) It must be as useful as or more useful than competitive medicines for a particular symptom or syndrome, or it must have a wide variety of approved medicinal uses.

It must not have more undesirable side effects than competitive medicines.

It must have a mode of delivery which is as good as or better than available alternatives.

It must be priced competitively.

It must have a risk-benefit ratio which is at least as good as that of competitive medicines.

It must not be restrictively scheduled under the federal Comprehensive Drug Abuse and Control Act. The more restrictive the schedule, the more serious impact on marketability and the cost of development.

Now compare the anticipated analogs with whole marihuana:

Except in a few situations, such as intravenous injection in an unconscious person, analogs or combinations of analogs are unlikely to be more useful than natural cannabis for most specific symptoms. Nor are they likely to have a much wider range of therapeutic uses than the natural product, which contains the cannabinoids (and synergistic combinations of cannabinoids) from which the analogs are derived. In fact, one result of the development of new analogs may be to identify new compounds for marihuana in its natural form. Shortly after dexamabinol, which is both a potent antioxidant and an NMDA antagonist, was found to protect brain cells against damage after a stroke or trauma, it was shown that THC and cannabidiol, also antioxidants, provide the same kind of protection. In fact, given the urgency of retarding the pathological processes

by a stroke or brain trauma, it may be more medically sensible to allow patients with closed head injuries to smoke accessible marihuana immediately upon regaining consciousness as they await transportation to a hospital to receive dexamethasone.

The analogs may not cause such minor side effects as inflammation of the sclera of the eyes or increased heart rate, which are not medically significant. Except for infrequent orthostatic hypotension (faintness on standing up), pulmonary effects from smoke and, in the opinion of some, the psychoactive effect (the high), marihuana has few medically significant side effects.

Inhalation devices now being perfected protect the lungs by separating the cannabinoids in whole marihuana from tar and other products. When these devices are manufactured in large numbers, they will provide an inexpensive, safe, and highly efficient means of delivery. Again, except for a few situations such as unconsciousness and pulmonary impairment, it is doubtful that a better means of delivery will be available for analogs.

Given the cost of development, the new analogs will be expensive. They will probably cost much more than whole marihuana even at the inflated prices imposed by the prohibition tariff. Suppose, for example, that a new analog is as effective as ondansetron in effectiveness and price. Today a patient suffering from nausea of cancer chemotherapy might require one to four 8-mg ondansetron pills at \$30 to \$40 apiece. Many patients probably get equally effective relief from a few puffs of a marihuana cigarette—cost \$5 at today's street price, 30 cigarettes of marihuana is produced as a medicine.

The potential benefits of whole smoked marihuana are extraordinarily high compared to the risks. For example, the therapeutic ratio of marihuana is not known because it has never caused an overdose death. It has been estimated on the basis of extrapolation from animal data to be 20,000 to 40,000 to 1. Even if the therapeutic ratio of a new analog is also high, it is unlikely to be as safe as whole marihuana because it will be physically possible to ingest much more of the analog than whole marihuana.

Any new cannabinoid analog with psychoactive properties would presumably have to be placed in a restricted schedule by the federal government. The United Corporation, which makes dronabinol, is now attempting to have it transferred from Schedule II to Schedule III. That would allow physicians to write prescriptions which could be refilled up to three times, reducing inconvenience and cost to the patient. Yet THC in the form of dronabinol is chemically the same as the THC in whole marihuana, which remains in Schedule I. It will become increasingly difficult to justify such inconsistencies, which will be regarded as hypocritical.

Ultimately, I do not believe the full potential of cannabinoids as medicines can be realized through the use of prescription analogs as long as the crushing, costly prohibition on natural marihuana is maintained. Will prescription analogs be available for all of the present and future medical uses of whole cannabis? If not, will off-label prescriptions of the analogs be available? And if prescription drugs are available, will they always be sought? For example, minor stomach upset is almost always relieved with a few puffs of cannabis. Will people suffering from this symptom go to the trouble and expense of seeking a prescription? When it is generally appreciated that marihuana usually relieves not only gastric distress, but many other symptoms such as headache, insomnia, tension, pain and dysphoria, it may come to be regarded much as aspirin.

In fact, the range of beneficial uses of marihuana is so broad that it may ultimately be wrong to single out the strict medical uses for approval. Many people use it not only to ease everyday discomforts, but also to heighten creativity or help with work. It can serve as an intellectual stimulant, promote emotional intimacy, or enhance the appreciation of food, sex, beauty, music, and art. Cannabis use simply cannot be made to conform to the boundaries established by present medical institutions. In this case the demand for legal enforcement of a distinction between medical and nonmedical use is incompatible with the realities of human need. I know that to say this is to invite the charge that medical marihuana is only using medicine as a stalking horse for the legalization of nonmedical use. This false accusation is actually a distortion of the view taken by enemies of marihuana. They are unwilling to admit that it can be a safe and effective medicine largely because they are committed to exaggerating its dangers when used for other purposes. Nevertheless, it will be hypocritical to deny that there is a connection. For 28 years I have been urging the legalization of marihuana for general use. At one time I thought medical use could be treated as a distinct issue, because even people who might never see the benefits of legalizing nonmedical use would respond to medical need. Now I have changed my mind. On the contrary, I believe that making marihuana fully available as a medicine is one of the reasons for general legalization.

Ideally, cannabis should be available under more or less the same rules now applied to alcohol. At present, I fear, the medical and legal system is too ossified to accommodate that change. But I believe enforcement of the laws against marihuana



increasingly neglected because of the same kind of public pressure that has led to the enactment of the medical n initiatives in five states. If I am correct, anti-marihuana statutes will come to resemble the laws against oral sex wh in several states but are ignored so totally that most people do not even know they exist. As the number of people possession declines, cannabis in its natural form, along with isolated cannabinoids and analogs, will be used more medicine. As a result, the public will be in a better position to learn about its virtues, and our understanding of thos in turn make the laws more difficult to enforce. I hope and expect that this process will bring the era of prohibition t end. Only then will it be possible to realize the full potential of this remarkable substance, and its medical potential

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